

# Breakout Group C (Day 2)

*Discuss the utilization of two different laboratory designations: tier (per Maputo document) vs. biosafety level*

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# Question 1: Should the laboratory tier designations and biosafety level designation be integrated?

- Tier level (Maputo designation) is based on services
  - Appendix E – describes biosafety capacity at different tiers
- Is there a way to integrate these tiers of services w/BSL categorization?
- **Integrating the designation is very difficult and different - since the health care facility is independent of a presenting “risk”**
  - E.g.: Ebola presents at primary health care centers
  - BSL designation may be relevant in US and high-income countries but not in low-income settings
- Biosafety level encompasses a combination of 4 elements: facility, equipment, practices, occupational health

# Discussion:

- Biosafety pertains to “management systems” that aren’t related to capacity
- A tier 4 does not relate to a BSL IV
- Need for **risk assessment** in every facility
  - E.g., Egypt where pathogens are presenting out of sync with their “tier”
- Need to go “case-by-case” situation
- Tier gives MOH an understanding of regional services and testing capacity
- However “safety” capacity needs to be present everywhere
- What are the key components of safety capacity – how can they relate to one another?
- Tier relate to laboratory function and service – which is defined equipment and personnel training
- Biosafety pertains to “management systems” which isn’t related to capacity

# Discussion:

- Suggested approach:
- Tier Activities – conduct a **“risk assessment”** by the four discrete components of biosafety: (i) facility, (ii) equipment, (iii) practices, (iv) occupational health
- Need guidance in pre-assigning **“risk assessment” – based on experience from vertical disease programs**
- Are local lab techs be capable of doing the **risk assessment**?
  - Team approach recommended that includes” SMEs & local expertise
  - But is this approach practical for scale-up?
  - How do we fulfill the needs of hundreds of low level labs that are in place?
  - Also, how do you translate this approach from a vertical program to an epidemic problem?

# Discussion:

- For vertical programs the biosafety **“risk assessment”** can be done in advance (based on the local environment): e.g., SMEs, lab techs, biosafety officer.
- Local teams need to be empowered to do the assessment themselves, which can be facilitated with the draft biosafety check list
- **Maybe make the risk assessment piece clearer**
- Regarding scale-up:
  - Reinforcement of biosafety check list – talks about **sustainable prevention**
  - IHR and GSHA emphasizes early detection and early response
- Need to clarify the application and purpose of the myriad tools that have been published - per situation so that local staff aren't confused with tool application

# Discussion/Recommendation:

- Useful to have a questionnaire and tool as a starting point for countries without any resource; but what about countries w/tools in place that conflict with those tools developed by outside experts?
- It was noted that IHR lab assessment tools – have a small portion of biorisk assessment
- Concern that this check list may overlap with WHO check list from an international body
- Does PEPFAR check list unnecessarily overlap with WHO check list?
- CEN tool vs. PEPFAR tool are they simple and how do they interact?

## Question 2: What are the laboratory tiered and biosafety level recommendations for point-of-care testing?

- Unresolved question w/in academic discussions
- One point of view: You have to sit down and evaluate the 13 elements in the draft biosafety check list.
  - You need a menu of elements to review and assess
  - Value: easy to deploy, easy to implement, will at a minimum will raise the awareness and provides measurement
- Opposing viewpoint: You need to know what is going on. And if you can score these elements – then you can score the “risks assessment” at the local level and decide their local mitigation options